

REMARKS/ARGUMENTS

The claims under consideration are 1-15.

In the Office Action dated November 14, 2006, the Examiner indicated that Claims 1-15 are allowable and that the only rejected claim was Claim 16, which was subsequently cancelled.

In the Office Action dated April 17, 2007, the Examiner rejected Claims 1-15 without formally withdrawing the allowability of Claims 1-15 and re-opening prosecution.

The Examiner has now rejected Claims 1-15 under 35 U.S.C. §103(a) as being unpatentable over Wu et al. (U.S. Patent 6,262,030) in view of Djokic et al. (U.S. Patent 4,886,792).

Applicants request reconsideration in view of the following:

The Examiner makes the argument that the only difference between the claimed compound and the reference to Wu is the substituent at position 3 of the 15 membered ring, hydroxyl group of the claimed compound as opposed to the keto group of the Wu et al. reference and that since reference to Djokic et al. discloses a hydroxyl group at the same position it would be obvious to substitute a hydroxy group for the keto of Wu in the expectation of obtaining compounds having the same activity. However there are substantial differences between the claimed compounds, and that of Wu to render the instantly claimed compounds unobvious over Wu alone or in view of Djokic et al.

Wu et al., at position 11 (structural formula on column 8) have a Y² substituent that is defined as a C₁-C₁₆ alkoxy group, -C(O)NH(C₁-C₁₆) alkyl, or -OC(O)NH(C₁-C₁₆) alkyl, wherein the alkyl moieties of the Y² groups are optionally substituted by an R₁₂ group or 1 to 3 halo groups or together Y² and Y³ are taken together to form an oxazolidin-2-one ring. In no case the Y² substituent of Wu et al. is a hydroxyl group as instantly claimed, nor is there any motivation to change the Y² of Wu to a hydroxyl group either alone or in view of Djokic

et al. since one skilled in the art would find no motivations to change Wu at positions in the expectation of obtaining compounds having similar activity.

Djokic et al. attribute the activity of this compound to the removal of both the cladinose and desosamina residue from the corresponding azithromycin derivative.

The Djokic et al. patent states that at concentration of 10^{-5} DESAZ, i.e. the azithromycin derivative obtained from the removal of cladinose residue only, shows an approximate equal activity as D-PEN in concentration of 10^{-7} (see column 5, lines 10-12). This means that DESAZ requires a concentration of two magnitude orders higher than the concentration of D-PEN to have similar activity. AZER i.e. the azithromycin derivative obtained from the removal of both cladinose and desosamina residues, has a similar activity as D-PEN or in concentration of 10^{-7} , a stronger one (see col. 5 lines 18-19).

From the Diagram 3 of Djokic et al. the *in vivo* activity of DESAZ is lower than D-PEN and DICL and far lower than the *in vivo* activity of AZER.

Accordingly, there is indication that the activity in the Djokic et al. patent is linked to the removal of both cladinose and desosamina residue, and that one skilled in the art would have been motivated to modify the compounds of Wu et al. by removing the desosamina residue at position 5 of Djokic et al. and expect to obtain compounds having improved anti-inflammatory activity.

Obviousness cannot be established by combining the teachings of prior art to produce the claimed invention absent some teaching, suggestion or incentive supporting the combination when the incentive to combine the teachings of the references is not immediately apparent, it is the duty of the Examiner to explain why the combination of the teaching is proper.

The mere fact that references can be combined does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination.

Citing references which merely indicate that isolated elements and/or features recited in the claims are known is not sufficient basis for concluding that the combination of the claimed elements would have been obvious. The references viewed by themselves and not in retrospect, must suggest doing what applicants have done.

The mere allegation that the difference between the claimed subject matter and the prior art is obvious does not create a presumption of unpatentability which forces an Applicant to prove conclusively that the Patent Office is wrong. The ultimate legal conclusion of obviousness must be based on facts, or records, not on the Examiner's unsupported allegation that a particular modification is well known, and thus obvious.

Applicants respectfully request that the rejection of Claims 1-15 be withdrawn as being unpatentable over Wu et al. in view of Djokic et al.

Applicants respectfully submit that all of the presently pending claims in this application are now in immediate condition for allowance. Accordingly, the Examiner is requested to pass this application to Issue.

Respectfully submitted,

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